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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/875,264	06/07/2001	Smita K. Nair	1579-579	5191

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EXAMINER	
WILSON, MICHAEL C	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 08/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/875,264	NAIR ET AL.	
	Examiner	Art Unit	
	Michael C. Wilson	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 February 2004 and 21 June 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19 and 39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19 and 39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6-7-01;2-3-04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *1449s filed 4-30-04 and 5-3-04*.

DETAILED ACTION

Claims 1-18 and 20-38 have been cancelled. Claim 39 has been added. Claims 19 and 39 are under consideration in the instant office action.

Applicant's arguments filed 2-8-04 and 6-21-04 have been fully considered but they are not persuasive. In the response filed 6-21-04, applicants state that a request to hold the provisional double patenting rejection in abeyance is a proper response to a provisional double patenting rejection. Applicants' statement is in error. However, to expedite prosecution, the response filed 6-21-04 is being considered "responsive."

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claim 19 remains rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of making cytotoxic T lymphocytes (CTL) comprising: i) introducing RNA encoding an antigen into antigen-presenting cells (APC) *in vitro*, wherein said RNA is isolated from tumor cells or pathogens, thereby producing APC that functionally present said antigen on their surface; ii) contacting the APC produced in step i) with lymphocytes *in vitro*, wherein the lymphocytes comprise cytotoxic T-lymphocytes (CTL), thereby producing CTL that recognize said antigen; and iii) maintaining the CTL produced in step ii) in culture, does not reasonably provide enablement for tumor-specific or pathogen-specific RNA (claim 19, ii, lines 4 and 5), merely contacting a T-cell with an RNA loaded APC that does not functionally present

on their surface an antigen encoded by the RNA (claim 19), or providing any T lymphocyte to obtain a CTL (claim 19). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims for reasons of record.

The specification teaches isolating total RNA from tumor cells, transfecting APC with the RNA to make APC that functionally express antigens encoded by the RNA on their surface. The APC are contacted with CTL to stimulate a CTL response against the antigen encoded by the APC, which is measured using a cytotoxicity assay (pg 22, line 8, through pg 23, line 5).

The specification does not teach how to isolate RNA that is specific to pathogens or tumors (claims 19, ii, lines 4-5). The specification does not teach how to separate RNA that is specific to pathogens or tumors from non-specific RNA. One of skill would not know how to separate tumor- or pathogen-specific RNA from non-specific RNA and would require undue experimentation.

The specification does not teach how to use an APC that does not express an antigen encoded by the RNA (claim 19, ii). Expression of an antigen on the surface of the APC is essential to stimulate CTL that recognize an antigen that is encoded by the RNA.

The specification does not teach how to contact any T lymphocyte as broadly claimed with the RNA-loaded APC to obtain CTL (claim 19, ii, line 1). T-lymphocytes encompass helper and cytotoxic T-cells. Thus, the claim encompasses contacting

RNA-loaded APC with helper T-cells to obtain CTL. However, helper T-cells cannot become CTL. It would have required one of skill in the art at the time the invention was made undue experimentation to determine how to combine T-cells as broadly claimed with APC expressing an antigen to obtain CTL. Therefore, the T-lymphocytes in the claim must at least comprise CTL.

Applicants have not addressed these rejections.

Claim Rejections - 35 USC § 102

The rejection of claim 20 under 35 U.S.C. 102(b) as being anticipated by Rouse (1994, J. Virol., Vol. 68, pg 5685-5689) has been withdrawn because claim 20 has been canceled.

Double Patenting

Claim 19 remains and claim 39 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 6,670,186 in view of the disclosure of '186. Although the conflicting claims are not identical, they are not patentably distinct from each other because the steps of claims 19 and 39 are a genus to the methods of claims 1 and 8 of '186. In particular, claims 1 and 8 of '186 require the steps of claims 19 and 39 as claimed in the instant application. Claims 1 and 8 require providing T cells, contacting the T cells with RNA loaded APCs and obtaining CTL as do claims 19 and 39. in view of the disclosure of

'186, the cytotoxicity assay in claim 1, step iv) of '186 requires maintaining the T cells under conditions conducive to CTL proliferation as in claim 19 of the instant invention.

Applicants have not addressed this rejection.

Claims 19 and 39 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,387,701 in view of the disclosure of '701. Although the conflicting claims are not identical, they are not patentably distinct from each other because the steps of claims 19 and 39 are a genus to the methods of claim 1 of '701. In particular, claim 1 of '701 requires the steps of claims 19 and 39 as claimed in the instant application. Claim 1 requires APCs with tumor RNA, contacting the APCs with T cells and obtaining effector cells that recognize antigens as do claims 19 and 39. In view of the disclosure of '701, the effector cells of claim 1 are CTL. The cytotoxicity assay in claim 1, step 4) of '701 requires maintaining the T cells under conditions conducive to CTL proliferation as in claim 19 of the instant invention.

Claims 19 and 39 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-29 of U.S. Patent No. 6,306,388 in view of the disclosure of '388. Although the conflicting claims are not identical, they are not patentably distinct from each other because the steps of claims 1-29 are a genus of claims 19 and 39 in the instant application. In particular, claim 1 in '388 is required in steps of claims 19 and 39 as claimed in the instant application. Claim 1 of '388 requires providing APCs loaded with tumor RNA or

pathogen RNA. In view of the disclosure of '388, these APCs can be used to make antigen-specific CTL as in claims 19 or 39 of the instant invention.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

No claim is allowed.

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached at the office on Monday, Tuesday, Thursday and Friday from 9:30 am to 6:00 pm at 571-272-0738.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on 571-272-0804.

The official fax number for this Group is (703) 872-9306.

Michael C. Wilson

MICHAEL WILSON
PRIMARY EXAMINER